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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,046	09/27/1999	THOMAS MEADE	A-58634-6/RF	9059

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EXAMINER

JONES, DAMERON

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,046

Applicant(s)

MEADE ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2004 and 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,30,32,41,45,48,49 and 58-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,30,32,41,45,48,49 and 58-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: response to petition.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/17/04 wherein the specification was amended. In addition, the amendment filed 12/17/04 is acknowledged wherein claims 1-21, 23-29, 31, 33-40, 43, 44, 46, 47, and 50-57 are canceled and claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 are amended.

Note: Claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 are pending.

RESPONSE TO APPLICANT'S AMENDMENT

2. The Applicant's arguments filed 12/17/04 and 11/17/04 to the rejection of claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed non-persuasive for the reasons set forth below.

112 (New Matter and Written Description) Rejections

I. The rejection of claims 61, 62, 65, and 66 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 8/10/04 and those set forth below.

II. The rejection of claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 under 35 USC, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 8/10/04 and those set forth below.

Applicant's assertions may be summarized as follows: (a) the specification at pages 21-22 teaches the nature of blocking agents and depends on the target

substance to be detected or visualized. (b) At the time the application was filed, peptides substrates comprising caspase sensitive sequences were known in the art. It is noted that Applicant has submitted documents indication that caspase sequences are known in the art.

(c) The specification as filed discloses identifying characteristics of sequences such that a skilled practitioner would be able to predict the structure of the claimed invention. (d) Claims 22, 30, 32, 41, 42, 45, 49, and 58-66 disclose peptide substrates comprising caspase sensitive sequences.

In regards to Applicant's comments that the submitted articles disclose amino acid sequences that read on the instant invention, the following response is set forth. An inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition and/or method for which patent protection is sought. The instant invention does not clearly set forth what is being claimed. What the reader extracts from the claims/specification is a desire, plan, or first steps for obtaining a desired result. It is noted that in the independent claims, the peptide is defined by a description of a particular type of enzyme. However, an adequate written description requires a precise definition such as by sequence, not a mere desire or plan for obtaining the claimed invention. Thus, claiming all peptides that interact with caspase (see independent claims) without defining what peptide sequences are compatible with the instant invention is not in compliance with the description requirement.

The instant application does no more than describe peptides generally and contains no information by which a person of ordinary skill in the art would understand that the invention possessed the claimed invention (i.e., caspase peptide sequences). Furthermore, the instant application does not specify which peptide sequences have the desired characteristics of interacting with the peptide such that T1 changes to meet the requirements set forth by Applicant.

In regards to the method claims, the methods depend upon finding a peptide-linker-chelator complex that results in a change in T1. Without such a complex, it is impossible to practice the instant invention. Generating a method wherein possession of a substance that is essential to practicing the method is not set forth results in an invention that is more theoretical than real.

While it is recognized that Applicant did apparently make some discovery, the critical step(s) of actually generation an applicable peptide sequence or at least developing a process through which one skilled in the art would be directly led to such a compound is absent. Thus, absent an essential portion of the invention results in an incomplete invention. Hence, knowing the starting point of an invention is not enough when specific peptides are necessary to operate or understand the invention.

112 Second Paragraph Rejection

The rejection of claims 30, 32, 41, 48, 63, and 64 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 8/10/04 and those set forth below.

Applicant asserts that the phrase 'under condition whereby said peptide interacts with caspase' is definite based on the specification (pages 20-21) which discloses what is meant by 'capable of interaction with a target substance'.

It should be noted that the Examiner was requesting clarification of the phrase 'under condition whereby said peptide interacts with caspase', not 'capable of interaction with a target substance'. However, having reviewed pages 20-21 of the specification, the phrase was still not found definite for reasons of record in the office action mailed 8/10/04.

103 Rejections

I. The rejection of claim 22 under 35 USC 103(a) as being unpatentable over Gries et al (US Patent No. 5,648,063) is MAINTAINED for reasons of record in the office action mailed 8/10/04 and those set forth below.

Applicant asserts that Gries et al does not disclose or suggest the instant invention because the reference does not teach the use of a peptide blocking moiety that is capable of interacting with a target substance such that the blocking moiety stops occupying at least one coordination site of the metal ion complex when the target substance is present.

Applicant's argument is non-persuasive because the intended use of a product does not carry patentable weight since patentability is based on the components present in the product. However, intended use does carry patentable weight in a method of use claim.

II. The rejection of claims 30, 32, 41, 42, 45, 48, 49, and 58-60 under 35 USC 103(a) as being unpatentable over Gries et al (US Patent No. 5,648,063) in view of Zychlinsky et al (US Patent No. 5,972,899) is MAINTAINED for reasons of record in the office action mailed 8/10/04 and those set forth below.

Applicant asserts that the Gries et al does not suggest or teach a blocking moiety that is capable of interacting with a target substance such that the blocking moiety stops occupying at least one coordination site of the metal ion complex when the target substance is present.

Applicant's argument is non-persuasive because the intended use of a product does not carry patentable weight since patentability is based on the components present in the product. However, intended use does carry patentable weight in a method of use claim.

In regards to the method claims cited in the rejection, it should be noted that Gries et al disclose compositions comprising a chelate complex which is used for magnetic resonance imaging. Thus, the limitations of Applicant's method claims are disclosed in the cited prior art.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
Art Unit 1616

April 14, 2005